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A clinical study to assess the safety, tolerability, and how the body distributes a new oral medicine called hyaluronyl carnosine amide solution in healthy participants

Submission date 03/07/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 06/07/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 06/07/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at how safe a new drug called FID-136 is, how well people tolerate it, how it behaves in the body, and whether it affects certain biological markers. It is the first time this drug is being tested in humans. The study collects important information after giving both single and multiple doses to healthy volunteers.

Who can participate?
Healthy men and women aged 18-64 years can participate. They must comprehend the full nature and purpose of the study, including possible risks and side effects, and cooperate with the investigator to comply with the requirements of the entire study.

What does the study involve?
The study will be conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo, Switzerland.
Depending on which part of the study they join (Part A or Part B), participants may stay in the clinic until Day 2 or up to Day 15, respectively.
In Part A, participants may receive a single dose of 500 mg given once or a total dose of 1000 mg given in two administrations of FID-136 (two 500 mg administered every 12 h). In Part B, they may receive multiple doses of either 500 mg or 1000 mg of FID-136 (two 500 mg administered every 12 h). FID-136 will be taken by mouth as a solution provided in stick packs.
During the study, blood and urine samples will be collected. Participants in Part B will also have a sample of synovial fluid taken from the knee at the end of treatment, if possible.
Participants will also be asked to complete a questionnaire to evaluate the taste (palatability) of FID-136.
Participants will have vital parameters recorded at regular intervals. Physical examination will be performed at the beginning and at the end of the study. An ECG will be performed at the beginning, throughout, and at the end of the study.

What are the possible benefits and risks of participating?
This is the first time FID-136 is being tested in humans, so its safety in people is not yet known. However, studies in animals did not show harmful effects.
Some study procedures may cause minor discomfort, such as blood sampling (which may cause pain, bruising, or bleeding) and, in Part B, a knee fluid sample (which may cause temporary pain or swelling).
Participants are not expected to receive direct health benefits from taking part. However, they will receive thorough medical check-ups before and after the study.
Participants will be closely monitored throughout the study, and their safety will be regularly reviewed.

Where is the study run from?
The study will be conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo (Switzerland)

When is the study starting and how long is it expected to run for?
July 2026 to February 2027

Who is funding the study?
Fidia Farmaceutici S.p.A. (Italy)

Who is the main contact?
Dr Milko Radicioni, clinic@croalliance.com

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Additional identifiers

Sponsor Study code
RRG2_25_01

Study information

Scientific Title
A Phase I, two-part study to investigate safety, tolerability and pharmacokinetics of FID-136 (hyaluronyl carnosine amide solution) administered orally to healthy participants

Acronym
FID-136 safety and tolerability

Study objectives
The clinical study will involve 26 male and female healthy participants: 16 in Part A and 10 in the following Part B.

The primary objective of study Part A is to evaluate the safety and tolerability of FID-136 across two dose levels (500 and 1000 mg) administered to healthy participants as a single administration.

The primary objective of study Part B is to evaluate the safety and tolerability of the dose level of FID-136, identified in study Part A, when administered as repeated doses to healthy participants for 14 consecutive days.

The secondary objectives of study Part A are:
1. To evaluate the pharmacokinetic profile of FID-136's main metabolites in plasma and urine after single administration of each of the 2 dose levels (500 and 1000 mg) of FID-136 to healthy participants. The main metabolites that will be quantified are 2-mer-carnosine and 2-mer-β-alanine.
2. To evaluate the palatability of FID-136.

The secondary objectives of study Part B are:
1. To evaluate the pharmacokinetic profile of FID-136's main metabolites in plasma and urine when the dose level of FID-136 identified in study Part A is administered as repeated doses to healthy participants for 14 consecutive days. The main metabolites that will be quantified are 2-mer-carnosine and 2-mer-β-alanine.
2. To evaluate the palatability of FID-136.

The exploratory objective of study Part B is:
1. To evaluate the presence and concentration of FID-136 main metabolites and selected

biomarkers in the synovial fluid after repeated administrations of FID-136 to healthy participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/04/2026, Canton Ticino Ethics Committee (c/o Ufficio di Sanità Via Orico, 5, Bellinzona, 6501, Switzerland; +41 (0)918143057; chantal.corti-ponti@ti.ch), ref: 2026-00585; Rif. CE 5103

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Sequential

Purpose
Early phase study focused on safety, tolerability and pharmacokinetics in healthy participants

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers (no specific condition studied at this stage). Therapeutic area: Rheumatology.

Interventions
Test product: Hyaluronyl carnosine amide solution (FID-136) 500 mg ready-to-use oral solution (stick pack), Fidia Farmaceutici S.p.A., Italy. In both study parts, to guarantee their safety, the participants will be divided into cohorts, further subdivided into smaller subgroups.

In study Part A, the participants will be enrolled in two consecutive cohorts, including eight healthy participants each; they will be divided into subgroups. Each cohort will receive the scheduled dose of investigational medicinal product, as follows:
Cohort 1: 500 mg (D1): one stick pack of FID-136 500 mg oral solution at 08:00 ± 1 h of Day 1
Cohort 2: 1000 mg (D2) administered every 12 h as one stick pack of FID-136 500 mg oral solution at 20:00 ± 1 h of Day -1 followed by one stick pack of FID-136 500 mg oral solution at 08: 00 ± 1 h of Day 1.

In each cohort, the first two groups (Groups 1, 2, 4, and 5) will include two participants each, while the third group in each cohort (Groups 3 and 6) will include four participants. The subjects

of groups 2, 3, 5, and 6 will be exposed to the treatment under investigation only after the evaluation by the Investigator of the safety data collected up to 24 h post-dose in the previous group and according to the stopping rules provided below.

At the end of Cohort 1, before proceeding to Cohort 2, safety and tolerability results (all the safety data) up to Day 8 will be evaluated by a Data Safety Monitoring Board. Predefined stopping rules will be considered for the decision to continue with the next cohort.

At the end of study Part A, before proceeding to study Part B, safety and tolerability results (all the safety data) up to Day 8 of Cohort 2 will be evaluated by a Data Safety Monitoring Board, and the dose to be used in study Part B will be identified.

Part B of the study:
The dose level of investigational medicinal product, identified in study Part A, will be administered as daily repeated doses for two consecutive weeks (14 days) to one cohort (i.e., cohort 3) of 10 healthy subjects.

The investigational medicinal product will be orally administered once a day from Day 1 to Day 14, at 8:00±1 h, if D1 is selected for a total of 14 administrations, or every 12 h from Day -1 at 20: 00 ± 1 h up to the morning of Day 14 at 8:00±1 h, if D2 is selected, for a total of 28 administrations.

The repeated dose cohort will be subdivided into two groups: the first group (Group 7) will include three participants, while the 2nd group (Group 8) will include seven participants. The participants of group 8 will be exposed to the treatment under investigation only if the Investigator's evaluation of the previous group's safety data (treatment-emergent adverse events) up to Day 15 post-dose is satisfactory.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Hyaluronyl carnosine amide solution

Primary outcome(s)
1. Treatment-emergent adverse events measured using adverse events monitoring at throughout the whole study

2. Vital signs (blood pressure, heart rate) measured using a sphygmomanometer at Study Part A: at Screening; Day -1; Day 1, before the morning administration (0) and 3, 4, 7 and 9 h after the morning administration; Day 2 at 24 h after the morning administration (Final visit measure) /ETV; Follow-up visit. Study Part B: at Screening; Day -1; on Day 1-2 and Day 14-15, at pre-dose (0) and 3, 4, 7, 9 and 24 h after the morning administration of Days 1 and 14; Day 3-13 at pre-dose in the morning ; ETV; Follow-up visit

3. Body weight measured using an electronic weighing scale at Study Part A: at Screening; Final visit/ETV; Follow-up Visit 6 (Day 8±1). Study Part B: at Screening; Day 2 at pre-dose, within a window of 1 h before dosing; Day 15 at 24 ± 1 h after the last morning administration (Final visit measure)/ETV ; Follow-up Visit 6 (Day 21±2)

4. Physical examinations results measured using visual physical examination at Study Part A: at Screening; Final visit/ETV; Follow-up Visit 6 (Day 8±1). Study Part B: at Screening; Final visit/ETV ; Follow-up Visit 6 (Day 21±2)

5. Clinical laboratory tests results (haematology, coagulation, blood chemistry and urinalysis) measured using clinical laboratory parameters analysis of venous blood samples collected from participants' forearm veins at Study Part A: at Day 2 at 24 ± 1 h after the morning administration (Final visit/ETV); Follow-up visit. Study Part B: at Day 2 at pre-dose, within a window of 1 h before dosing; Day 15 at 24 ± 1 h post the last morning administration (Final visit/ETV).

6. ECG recording measured using 12-lead ECGs recorded in supine position after 5 min at rest through an electrocardiograph at Study Part A: at Screening; Day -1, applicable to D2 only; Day 1 at pre-dose, applicable to D1 only, and 7 h after the morning administration; Final visit/ETV; Follow-up visit. Study Part B: at Screening; Day -1, applicable to D2 only; Day 1 at pre-dose, applicable to D1 only, and 7 h after the morning administration; From Day 2 to Day 13 at pre-dose in the morning; Day 14 at pre-dose and 7 h after the last morning administration; Day 15 at 24 h post the last morning administration (Final visit measure)/ETV; Follow-up visit.

Key secondary outcome(s)

1. Part A. FID-136 main metabolites' concentration and pharmacokinetic profile in plasma (Cmax, tmax, AUC0-t and other parameters as appropriate) after single dose of FID-136 measured using venous blood samples collected from participants' forearm veins at at pre-dose (0), 2, 6, 10, 12, 14, 16, 18, 20 and 24 h post-dose

2. Part A. Urine FID-136 main metabolites' concentration, the excreted daily amount (Ae0-24) and renal clearance (Clr) measured and calculated up to 24 h after single dose of FID-136 measured using urine collection at in the intervals 0-6, 6-12, 12-18, 18-24 h post-dose

3. Part A. Subjective evaluation of palatability of FID-136 measured using palatability questionnaire at Day 1, 10 ± 5 min post-dose

4. Part B. FID-136 main metabolites' concentration and pharmacokinetic profile in plasma (Cmax, tmax, AUC0-t and other parameters as appropriate) after the first dose of FID-136, measured using venous blood samples collected from participants' forearm veins at at pre-dose (0) and 2, 6, 10, 12, 14, 16, 18, 20 and 24 h after the first dose

5. Part B. FID-136 main metabolites' concentration and pharmacokinetic profile in plasma (Cmax, ss, tmax,ss, AUCτ,ss and other parameters as appropriate) after the last repeated dose of FID-136 administered for 14 days of treatment, measured using analysing venous blood samples collected from participants' forearm veins at at pre-dose (0) and 2, 6, 10, 12, 14, 16, 18, 20 and 24 h after the last dose

6. Part B. Urine FID-136 main metabolites' concentration, the excreted daily amount (Ae0-24) and the renal clearance (Clr) after the first and the last repeated dose of FID-136 for 14 days of treatment, measured using urine collection at in the intervals 0-6, 6-12, 12-18 and 18-24 h after the first and the last morning administration

7. Part B. Subjective evaluation of the palatability of FID-136 measured using palatability questionnaire at Day 1 and Day 14, 10 ± 5 min post-dose

8. Part B, Exploratory. Measurement of the presence and concentration of FID-136 main metabolites and of selected biomarkers after the last repeated dose of FID-136 in the synovial fluid. As relevant biomarkers, the cytokines TNFα, IL-1β, IL-6, the chemokines MCP1, CCL5, CXCL8, CXCL1, CXCL2, CXCL6 and the metalloproteinases MMP-3 and MMP-13 will be investigated measured using knee arthrocentesis at Day 15 up to 6 h after 24 h post the last morning administration

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and age: men/women, 18-64 years old inclusive
3. Body Mass Index (BMI): 18.5-30 kg/m² inclusive
4. Vital signs: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, heart rate 50-99 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to cooperate with the Investigator and to comply with the requirements of the entire study
6. Contraception and fertility (women only): women of non-child-bearing potential or in post-menopausal status for at least 1 year, defined as such when there is either:
6.1. 12 months of spontaneous amenorrhea or
6.2. 6 weeks documented postsurgical bilateral oophorectomy with or without hysterectomy will be admitted. For all women, pregnancy test results must be negative at screening and on Day -1 of each study part.
7. Contraception (men only): males will either be sterile or agree to use one of the following approved methods of contraception from the first investigational medicinal product administration until at least 90 days after the last administration, also in case their partner is currently pregnant:
7.1. A male condom with spermicide
7.2. A sterile sexual partner or a partner in post-menopausal status for at least 1 year
7.3. Use by the female sexual partner of an intra-uterine device, a female condom with spermicide, a contraceptive sponge with spermicide, a diaphragm with spermicide, a cervical cap with spermicide, or hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit
or:
True abstinence (i.e., refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the participant). Periodic abstinence (e.g., calendar, ovulation, thermal symptoms, post-ovulation methods), female sexual partner lactational amenorrhea, and withdrawal are not acceptable.
Men must agree to inform their partners of the participation in the clinical study. Furthermore, they will not donate sperm from the date of the informed consent form’s signature, throughout the study, and for at least 90 days after the last dose of the study treatment.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Electrocardiogram (ECG) 12-leads (supine position): clinically significant abnormalities
2. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Laboratory analyses: clinically significant abnormal laboratory values at screening indicative of physical illness
4. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that may interfere with the aim of the study
5. C-reactive protein: abnormal and clinically relevant at screening
6. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
7. Medications: non-steroidal anti-inflammatory drugs for one month or corticosteroids for 3 months or medications, including over-the-counter (OTC) medications, homeopathic preparations, vitamins, food supplements and herbal remedies for 3 weeks before the start of the study
8. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study
9. Blood donation: blood donations for 3 months before this study
10. Drug, alcohol, caffeine, tobacco: history of drug, alcohol (>1 drink/day for females and >2 drinks/day for men, defined according to the USDA Dietary Guidelines 2020-2025) caffeine (>5 cups coffee/tea/day) or tobacco (≥10 cigarettes/day) abuse
11. Drug test: positive result at the urine drug screening test at screening or Day -1
12. Alcohol test: positive alcohol saliva test at screening or Day -1
13. Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study; vegetarians and vegans; grapefruit or grapefruit juice for 48 h before the first investigational medicinal product administration
14. Pregnancy (women only): positive or missing pregnancy test at screening or Day -1; childbearing potential, pregnant or lactating women.

Date of first enrolment
13/07/2026

Date of final enrolment
01/02/2027

Locations

Countries of recruitment
Italy

Switzerland

Sponsor information

Organisation
Fidia Farmaceutici (Italy)

ROR
https://ror.org/00dy5wm60

Funder(s)

Funder type

Funder Name
Fidia Farmaceutici

Alternative Name(s)
Fidia Pharma, Fidia

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available